Saiber
ATTORNEYS AT LAW

Arnold B. Calmann
(973) 645-4828
abc@saiber.com

May 29, 2024

BY ELECTRONIC FILING **FILED UNDER SEAL**

Hon. Tonianne J. Bongiovanni, U.S.M.J.
Clarkson S. Fisher Federal Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *Arbutus Biopharma Corp et al. v. Pfizer Inc. et al.*, Case No. 3:23-cv-04200-ZNQ-TJB

Dear Judge Bongiovanni:

We represent Plaintiffs along with co-counsel for Arbutus Biopharma Corp., Morrison & Foerster LLP, and co-counsel for Genevant Sciences GmbH, Quinn Emanuel Urquhart & Sullivan, LLP. We are writing in advance of the Court's scheduled June 5, 2024 Status Conference to respectfully request an order compelling Defendants to produce samples of the Accused Product—a standard production and inarguably relevant to this matter—along with the other documents and materials discussed below.

As we explain herein, Plaintiffs have expended an exhaustive effort to attempt to amicably resolve these issues but to no avail. The matter is ripe for Your Honor's consideration and the entry of an Order compelling full, complete, and prompt production.

Background

This is a patent litigation in which Plaintiffs allege that Defendants' COVID-19 vaccine (the "Accused Product") infringes five of Plaintiffs' patents directed generally to systems for delivering nucleic acid to cells. Plaintiffs served document requests nearly 10 months ago and the parties have since met and conferred five times and exchanged 10 letters, but disputes remain concerning Defendants' refusal to produce (1) physical samples of the Accused Product and its ingredients, (2) noncustodial documents identified through a manual search, (3) certain research and development documents, (4) certain manufacturing documents, and (5) documents produced in a parallel patent litigation involving the Accused Product. The Court should compel production of those documents and materials for at least the reasons set forth below.

Argument

1. Physical Samples Of The Accused Product And Its Ingredients

[redacted]

[redacted]

[1] *See also Merck Sharp & Dohme Corp. v. Apotex Inc.*, No. 15-cv-2384 (D.N.J. 2017), Dkt. No. 189 (ordering production of samples); *Shire Dev. LLC v. Invagen Pharm. Inc.*, No. 15-cv-00367 (D.N.J. 2015), Dkt. No. 126 (ordering defendant to "create samples of its ANDA products and provide them to Plaintiff"); *Merck Sharp & Dohme Corp. v. Fresenius Kabi USA, LLC*, No. 14-4989 (D.N.J. 2014), Dkt. No. 86 (ordering defendant to "create laboratory scale samples of its accused NDA product and produce 35 vials"); *LifeSciences Corp. v. HyperBranch Med. Tech., Inc.*, No. CV 15-819-LPS-CJB, 2016 WL 675553, at *1 (D. Del. Feb. 12, 2016) (ordering production of samples of each accused product because "samples are indisputably relevant to the claims and defenses" in a patent infringement matter); *Procter & Gamble Co. v. Be Well Mktg., Inc.*, No. 12-MC-392, 2013 WL 152801, at *4 (M.D. Pa. Jan. 15, 2013) (compelling third party to produce samples of the accused product at its own cost, even though they would need to be continuously refrigerated); *Everlight Elecs. Co., Ltd. v. Nichia Corp.*, Civil Action No. 12–CV11758, 2013 WL 6713789, at *2 (E.D. Mich. Dec. 20, 2013) ("Courts recognize the essential nature of accused product samples in patent infringement cases.").

[redacted]

2. Manual Searches For Noncustodial Data

[redacted]

[redacted]

[redacted]

---

[2] [redacted]

[3] [redacted]

[redacted]

The Court should thus compel Defendants to conduct a manual search for responsive noncustodial documents. If the Court determines that is unreasonable, Defendants should be ordered to run the additional search terms Plaintiffs have proposed, without arbitrarily limiting them to ten.

3. Noncustodial R&D Documents Concerning The Entire Accused Product

RFP Nos. 4, 6-14, 16, 21, 40, 78, and 82 seek research and development documents concerning the entire Accused Product—*i.e.,* not only the LNP component of the Accused Product, but also the messenger RNA ("mRNA") component and all other components. *See* Ex. A. [redacted]

[redacted]

[redacted]

4 [redacted]

[redacted]

4. Manufacturing Documents

Plaintiffs' RFP Nos. 5, 15, and 17 seek documents relating to the process and components that Defendants utilize to manufacture the entire Accused Product. *See* Ex. A. Such documents are inarguably relevant to Plaintiffs' causes of action, including at least Plaintiffs' charges of infringement, which assert patents claiming, *inter alia*, "[a]n apparatus for producing a lipid vesicle encapsulating a nucleic acid" ('320 patent at 18:56-57), and "[a] process for producing a lipid vesicle encapsulating a nucleic acid" ('098 patent at 19:2-3). [redacted]

[5] *See* U.S. Patent 9,504,651 ("[a] lipid vesicle formulation comprising: … messenger RNA"); U.S. Patent No. 11,141,378 ("nucleic acid-lipid particle … wherein the RNA is an mRNA" and "pharmaceutical composition … wherein the mRNA is fully encapsulated in the nucleic acid-lipid particle"); U.S. Patent No. 11,318,098 ("process … wherein the RNA comprises an mRNA"); U.S. Patent No. 11,298,320 ("apparatus … wherein the RNA comprises an mRNA"). Each patent's specification states that the "RNA may be in the form of … mRNA." '378 Patent at 10:52:63; '651 Patent at 3:66-4:3; '098 Patent at 4:8-12; '320 patent at 4:8-12.

5. Documents Produced By Defendants In The *Alnylam* Litigation

Plaintiffs' RFP Nos. 88 and 89 request documents that Pfizer or BioNTech produced in another patent infringement case involving Pfizer's COVID-19 vaccine: *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc. and Pharmacia & Upjohn Co. LLC*, C.A. No. 22-cv-336-CFC (D. Del.). Ex. A at 90-91. Defendants objected, contending that the requested documents are irrelevant because *Alnylam* "involves different patents." Ex. B at 6. That is mistaken for multiple independent reasons and Defendants should thus be compelled to produce the requested documents.

First, *Alnylam* involves the *same accused product* and the *same claimed subject matter*. Specifically, Alnylam alleged that Defendants' Comirnaty vaccine, ***the Accused Product here***—infringes the claims of U.S. Patent No. 11,382,979, among others. Ex. G at 8-9, 15-18. And the claims of that patent overlap with those of U.S. Patent No. 8,492,359, one of the patents asserted here. For example, the '979 patent claims, *inter alia*, "[a] lipid particle comprising: . . . ***35-65 mol % of a cationic lipid***," and the '359 patent claims "[a] nucleic acid-lipid particle comprising: . . . "a ***cationic lipid comprising 50 mol % to 65 mol %*** of the total lipid present in the particle." Thus, proving infringement in both cases will involve comparing the same Accused Product to very similar patent claims making it likely that Defendants produced documents in *Alnylam* that are directly relevant to Plaintiffs' claims of infringement, as well as Defendants' defense of non-infringement, here. Courts have compelled the production of documents in parallel patent suits that, as here, concern the same underlying product and technology. *See, e.g., Alloc, Inc. v. Unilin Beheer B.V.*, 2006 WL 757871, at *5 (E.D. Wis. Mar. 24, 2006) (compelling the production of documents from a parallel infringement suit concerning the same accused product).

Second, the documents that Pfizer and BioNTech produced in *Alnylam* are also relevant to damages here. Defendants have asserted in both cases that the success of their COVID-19 vaccine resulted from their own ingenuity rather than that of Alnylam or Plaintiffs. *Compare* Ex. H at pp. 41-43, *with* Ex. I at pp. 53-58. Defendants are therefore likely to have produced documents in *Alnylam* regarding the market for their vaccine and purported noninfringing alternatives, which are relevant to determining, *e.g.*, a reasonable royalty. *See AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1338 (Fed. Cir. 2015) ("standard … reasonable royalty analysis takes account of the importance of the inventive contribution in determining the royalty rate that would have emerged from the hypothetical negotiation").

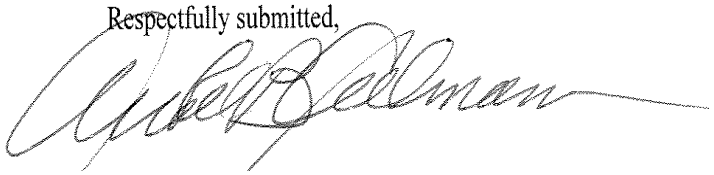
Third, given the clear relevance of the documents requested by RFP Nos. 88 and 89, Defendants must identify a burden that would justify refusing the discovery. *Barton v. RCI, LLC*, No. 10-3657 PGS, 2013 WL 1338235, at *3 (D.N.J. Apr. 1, 2013) ("'The party resisting discovery has the burden of clarifying and explaining its objections to provide support therefor.'") (quoting *Tele-Radio Sys. Ltd. v. De Forest Elecs., Inc.*, 92 F.R.D. 371, 375 (D.N.J. 1981)). They have not done so.[6] Nor can they because Plaintiffs do not seek the collection or review of any new documents. Rather, Plaintiffs only request documents that Defendants have already produced in

[6] The same is true for all of the categories of discovery addressed in this letter.

another case. Plaintiffs thus respectfully request that Defendants be compelled to produce the documents they produced in *Alnylam*.

We thank the Court for its consideration and assistance in this matter and look forward to hearing from the Court at its earliest convenience.

Respectfully submitted,



Arnold B. Calmann

cc: Counsel of record (by CM/ECF and electronic mail)